4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1867]

Novartis Pharmaceuticals Corp., et al.; Withdrawal of Approval of 13 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 13 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 003290	Neo-Calglucon (calcium glubionate) Syrup	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936
NDA 009816	Cortef Acetate S.E.E. Drops (hydrocortisone acetate) Ophthalmic Solution	Upjohn, a Pfizer Division, 235 East 42nd St., New York, NY 10017
NDA 009817	Cortef Acetate (hydrocortisone acetate) Ophthalmic Ointment, 1.5%	Do.
NDA 010645	Optef Drops (hydrocortisone probutate) Ophthalmic Solution, 0.2%	Do.
NDA 010155	Mytelase (ambenonium chloride) Tablets, 10 milligrams (mg)	Sanofi-Aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ, 08807
NDA 016659	Norinyl 1 + 50 (norethindrone and mestranol) Tablets, 1 mg/0.05 mg	Actavis Laboratories Ut, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 41 Moores Rd., Frazer, PA 19355
NDA 016807	Thyrolar (liotrix [tetraiodothyronine levothyroxine sodium (T4) and triiodothyronine liothyronine sodium (T3)]) Tablets, 0.0125 mg/0.0031 mg, 0.025 mg/0.0063 mg, 0.05 mg/0.0125 mg, 0.1 mg/0.025 mg, 0.15 mg/0.0375 mg, and 0.25 mg/0.0625 mg	Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940
NDA 017919	Ortho Novum 1/35 (ethinyl estradiol and norethindrone) Tablets, 0.035 mg/1 mg	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560
NDA 018768	VePesid (etoposide) Injection, 20 mg/mL	Corden Pharma Latina S.p.A., c/o Clinipace Inc., 1434 Spruce St., Suite 100, Boulder, CO 80302
NDA 019972	Ocupress (carteolol hydrochloride) Ophthalmic Solution, 1%	Novartis Pharmaceuticals Corp.
NDA 021590	FazaClo (clozapine) Orally Disintegrating Tablets, 12.5 mg, 25 mg, 100 mg, 150 mg, and 200 mg	Jazz Pharmaceuticals Ireland Ltd., c/o Jazz Pharmaceuticals, Inc., 3170 Porter Dr., Palo Alto, CA 94304
NDA 021664	Bromday/Xibrom (bromfenac) Ophthalmic Solution, Equivalent to 0.09%	Bausch & Lomb Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
NDA 022018	Lamivudine and Zidovudine Tablets, 150 mg lamivudine and 300 mg zidovudine	Pharmacare Ltd., c/o Lachman Consultants Services, Inc., 1600 Stewart Ave., Suite 604, Westbury, NY 11590

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved

new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: October 5, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-22402 Filed: 10/8/2020 8:45 am; Publication Date: 10/9/2020]